

1. Identification

Product identifier	Erythromycin Estolate		
Other means of identification			
Catalog number	1243002		
Chemical name	Erythromycin, 2'-propanoate, dodecyl sulfate (salt)		
Synonym(s)	Erythromycin propionate lauryl sulfate		
Recommended use	Specified quality tests and assay use only.		
Recommended restrictions	Not for use as a drug. Not for administration to humans or animals.		
Manufacturer/Importer/Supplier/Distributor information			
Company name	U. S. Pharmacopeia		
Address	12601 Twinbrook Parkway Rockville MD 20852-1790 US		
Telephone	RS Technical Services	301-816-8129	
Website	www.usp.org		
E-mail	RSTECH@usp.org		
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300	
	CHEMTREC outside US & Canada	+1 703-527-3887	

2. Hazard(s) identification

Physical hazards	Not classified.		
Health hazards	Acute toxicity, oral	Category 4	
	Serious eye damage/eye irritation	Category 2B	
OSHA hazard(s)	Not classified.		
Label elements			



Signal word	Warning		
Hazard statement	Harmful if swallowed. Causes eye irritation.		
Precautionary statement			
Prevention	Wash thoroughly after handling.		
Response	If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.		
Storage	Not available.		
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.		
Hazard(s) not otherwise classified (HNOC)	Not classified.		

3. Composition/information on ingredients

Substance

Hazardous components

Chemical name	Common name and synonyms	CAS number	%
Erythromycin Estolate	Erythromycin propionate lauryl sulfate	3521-62-8	100

4. First-aid measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a physician if symptoms develop or persist.
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.
Eye contact	Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Get medical attention if irritation develops and persists.
Ingestion	IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell. Rinse mouth thoroughly.
Most important symptoms/effects, acute and delayed	Irritation of eyes and mucous membranes.
Indication of immediate medical attention and special treatment needed	Treatment of overdose should be symptomatic and supportive. Perform gastric lavage. Administer activated charcoal as a slurry. Monitor vital signs. Monitor ECG. Monitor fluid and electrolyte status. Monitor liver enzymes. Monitor pancreatic enzyme levels. For allergic or anaphylactoid reactions, open airway and administer antihistamines, corticosteroids, and/or epinephrine. For moderate or severe pseudomembranous colitis, manage with fluids and electrolytes, protein supplementation, and treatment with an antibacterial drug clinically effective against <i>Clostridium difficile</i> colitis. Hemodialysis is unlikely to be of benefit. (Meditext); (PDR)
General information	Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media	Use fire-extinguishing media appropriate for surrounding materials. Water. Foam. Dry chemical or CO ₂ .
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.
Fire-fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Avoid inhalation of dust from the spilled material. Wear appropriate personal protective equipment.
Methods and materials for containment and cleaning up	Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid the generation of dusts during clean-up. For waste disposal, see section 13 of the SDS. Clean surface thoroughly to remove residual contamination.

7. Handling and storage

Precautions for safe handling	As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly.
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Exposure limit values

Industrial Use

Material	Type	Value
Erythromycin Estolate (CAS 3521-62-8)	TWA	0.2 mg/m ³

Biological limit values	No biological exposure limits noted for the ingredient(s).
Appropriate engineering controls	Airborne exposure should be controlled primarily by engineering controls such as general dilution ventilation, local exhaust ventilation, or process enclosure. Local exhaust ventilation is generally preferred to general exhaust because it can control the contaminant at its source, preventing dispersion into the work area. An industrial hygiene survey involving air monitoring may be used to determine the effectiveness of engineering controls. Effectiveness of engineering controls intended for use with highly potent materials should be assessed by use of nontoxic surrogate materials.
Individual protection measures, such as personal protective equipment	
Eye/face protection	Safety glasses with sideshields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.
Skin protection	
Hand protection	Chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic nonlatex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.
Other	For handling of laboratory scale quantities, a cloth lab coat is recommended. Where significant quantities are handled, work clothing may be necessary to prevent take-home contamination.
Respiratory protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Thermal hazards	Not available.
General hygiene considerations	Handle in accordance with good industrial hygiene and safety practice.

9. Physical and chemical properties

Appearance	White crystalline powder.
Physical state	Solid.
Form	Powder.
Odor	Odorless or practically odorless.
Odor threshold	Not available.
pH	Not available.
Melting point/freezing point	275 - 284 °F (135 - 140 °C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not applicable.
Upper/lower flammability or explosive limits	
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	< 0.0000001 kPa at 25 °C
Vapor density	Not available.
Relative density	Not available.
Solubility in water	Practically insoluble.
Partition coefficient (n-octanol/water)	0.04
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Macrolide antibiotic.
Molecular formula	C40H71NO14.C12H26O4S
Molecular weight	1056.39

Solubility (other)

Soluble in ethanol, in acetone, and in chloroform.

10. Stability and reactivity**Reactivity**

No reactivity hazards known.

Chemical stability

Stable at normal conditions.

Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid

None known.

Incompatible materials

Strong oxidizing agents.

Hazardous decomposition productsNO_x, SO_x. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.**11. Toxicological information****Information on likely routes of exposure****Ingestion**

Harmful if swallowed.

Inhalation

Due to lack of data the classification is not possible.

Skin contact

Due to lack of data the classification is not possible.

Eye contact

Causes eye irritation.

Symptoms related to the physical, chemical, and toxicological characteristics

Macrolide antibiotics: Nausea. Vomiting. Abdominal pain. Diarrhea. Taste perversion. Yellow eyes or skin. Hearing loss. Ringing in ears. Fever.

Delayed and immediate effects of exposure

Macrolide antibiotics: Cholestasis. Blood disorders. Ototoxicity. Superinfection. Pseudomembranous colitis. Irregular heart rate.

Cross sensitivity

Persons sensitive to other erythromycins or macrolides may be sensitive to this material also.

Medical conditions aggravated by exposure

Macrolide antibiotics: Liver or kidney impairment. Cardiac arrhythmias. Sjögren's syndrome. Myasthenia gravis. Porphyria. Hearing disorders.

Acute toxicity

Harmful if swallowed.

Product**Species****Test Results**

Erythromycin Estolate (CAS 3521-62-8)

Acute*Oral*

LD50

Mouse

> 6450 mg/kg

Rat

1447 mg/kg

Skin corrosion/irritation

Due to lack of data the classification is not possible.

Serious eye damage/eye irritation

Causes eye irritation.

Respiratory sensitization

Due to lack of data the classification is not possible.

Skin sensitizationDue to lack of data the classification is not possible.
A related material did not cause allergic skin reactions in animal tests.**Germ cell mutagenicity**Due to lack of data the classification is not possible.
Data from germ cell mutagenicity tests were not found.
The base of this material tested negative for mutagenicity in bacterial cells.**Carcinogenicity**Based on available data, the classification criteria are not met.
This material is not considered to be a carcinogen by IARC, NTP, or OSHA.
Long-term (2-year) oral studies in rats with erythromycin base did not provide evidence of tumorigenicity.**Reproductive toxicity**Based on available data, the classification criteria are not met.
Epidemiological studies have shown conflicting results concerning an association between therapeutic use of erythromycin during pregnancy and an increased risk of malformations.
In rats fed erythromycin at levels up to 0.25% in diet before, during, and after gestation, there was no evidence of teratogenicity, impairment of fertility, or other adverse effects on reproduction or development.**Specific target organ toxicity - single exposure**

Based on available data, the classification criteria are not met.

Specific target organ toxicity - repeated exposure

Based on available data, the classification criteria are not met.

Aspiration hazard

Based on available data, the classification criteria are not met.

12. Ecological information**Ecotoxicity**

No ecotoxicity data noted for the ingredient(s).

Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available.
Mobility in soil	Not available.
Other adverse effects	Not available.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Not available.
Hazardous waste code	Not available.
Waste from residues / unused products	Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as a hazardous material by DOT.

IATA

Not regulated as a dangerous good.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information available.

15. Regulatory information

US federal regulations CERCLA/SARA Hazardous Substances - Not applicable.
One or more components are not listed on TSCA.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories Immediate Hazard - Yes
Delayed Hazard - No
Fire Hazard - No
Pressure Hazard - No
Reactivity Hazard - No

SARA 302 Extremely hazardous substance No

SARA 311/312 Hazardous chemical No

Other federal regulations

Safe Drinking Water Act (SDWA) Not regulated.

Food and Drug Administration (FDA) Not regulated.

US state regulations California Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65): This material is not known to contain any chemicals currently listed as carcinogens or reproductive toxins.

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	Yes

Country(s) or region	Inventory name	On inventory (yes/no)*
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

16. Other information, including date of preparation or last revision

Issue date	12-04-2009
Revision date	05-23-2014
Version #	02
Further information	Not available.
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Revision Information	This document has undergone significant changes and should be reviewed in its entirety.